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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,120	10/20/2000	Dosuk D. Lee	04712/027002	7808

21559 7590 05/21/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

SHARAREH, SHAHNAME J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/21/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,120

Applicant(s)

LEE ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on March 05, 2003 has been entered. Claims 22-44 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment and arguments.

Claim Rejections - 35 USC § 112

Claims 24 stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record. Applicant's arguments have been fully considered but are not found persuasive, because they it does not specify which derivatives are applicant claiming? Accordingly the recitation of "derivatives thereof" encompass a plethora of compounds, the scope of which is not enabled.

Claims 24 stand rejected under 35 U.S.C. 112, second paragraph. The recitation of "derivatives thereof" in claim 24 renders the claim indefinite. The recitation of "derivatives thereof" encompass various possible moieties, the metes and bounds of which are not clear. Each individual compound of claim 24 can contain numerous functional or non-functional derivatives, however, specification fails to define the scope of such derivatives. Thus, the claim as a whole is indefinite.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamura et al (JPN. J. Pharamcol 65, 289-291 (1994), IDS filed on 12/6/2002) In view of Gerhart et al US Patent 5,085,861 and Constantz et al US Patent 5,782,971.

The instant claims are directed to paste compositions comprising calcium phosphate and an anticancer and kits thereof containing a second adjuvant and means to deliver the composition.

Yamamura discloses methods of implanting injectable doxorubicin loaded hydroxyapatite beads for treating tumor (abstract, entire page 289-291). The Ca/P raion of Yamamura's composition is 1.68. Yamamura does not specifically teach a paste formulation.

Gerhard disclose calcium phosphate containing compositions comprising biocompatible calcium phosphate ceramics that can be in the form of an injectable or moldable paste and will solidify within 10 minutes after administration. (see abstract; col 7, lines 30-46, 60-67; col 8, lines 1-20; examples 2-3). The particle size of Gerhard's compositions falls within the instantly claimed nanocrystalline (see col 7, lines 15-25). Gerhard's compositions contain active agents that are readily used in treatment of cancers such as bone tumor (col 13, lines 45-67). Gerhard finally discloses kits for preparing his composition for ease of use in a clinical or surgical setting (col 7, lines 42-49).

Constantz et al teach amorphous calcium phosphate containing compositions that are used as suitable drug delivery vehicles (col 2, lines 60-67; col 6, lines 61-63). Constantz specifically teaches paste formulations of calcium phosphate that are capable of hardening after administration at the site of interest (col 6, lines 40-64). Constantz's composition comprise about 15 wt% of the dry ingredient (solid component) having particle sizes of about 0.5- 500 microns (col 5 lines 1-3; and lines 14-25).

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Constantz further indicates that one of ordinary skill in the art would be able to modify the viscosity of his composition by varying the percentages of solids in his composition, thus allowing for ease of administration (col 6, lines 32-39). Constantz suggests the use of an additional calcium phosphate and also states that the calcium to phosphate ratio of such compositions should be about 1.6 to about 1.8 (see col 3, lines 5-20; col 5, lines 1-10, claims 1-5). Constantz finally suggests preparing kits to ease access and preparation (see col 7, lines 1-10). Constantz lacks the specific teaching of an anticancer agent in combination with the calcium phosphate vehicle.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify physical characteristics of Yammmura's composition into an injectable paste, as suggested by Gerhard and Constantz, and formulate a hardenable calcium phosphate formulation that is easily administered to a site of interest such as a tumor, because the ordinary artisan would have had a reasonable expectation of success in achieving the same results. Finally, the ordinary artisan would have had a reasonable expectation of success in preparing a ready to use kit for easing the access and use of such compositions at a clinical setting.

Double Patenting

Claims 22-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-44 of copending Application No. 09/692,664 for the reasons of record.

Conclusion

No claims are allowed. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on December 5, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
May 19, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200